

### Remarks

Reconsideration of the captioned application as amended herewith and in view of the following Remarks and Arguments is respectfully requested.

Claims 1 - 3, 5, 6, and 9 - 15 are pending in the application.

Claims 1 – 5 were rejected under 35 U.S.C. §102 (a) and (e) as being anticipated by Perricone (US 6365623) ("623"). Claims 1 – 3 and 5 were rejected under 35 U.S.C. §102 (a) and (e) as being anticipated by Perricone (US 6319942) ("942"). Claims 1, 2, and 10 were rejected under 35 U.S.C. §102 (a) and (e) as being anticipated by Ptchelintsev (US 5972993) ("993"). Claims 6 and 9 – 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Perricone '942 as applied to claims 1 – 3 and 5, further in view of De Lacharriere et al. (US 5968532) ("532").

#### The Rejections under 35 U.S.C. §102 (a) and (e) are Erroneous

In the Office Action, the Examiner stated that '623 taught a method of treating acne by applying a composition to the skin. The composition of the '623 patent may include adjunct ingredients. The disclosure of the '623 patent includes dimethylaminoethanol and tyrosine in a broad list of adjunct ingredients (column 5, lines 40 – 46). The Examiner asserts that this language anticipates the present claimed invention. Applicants strongly disagree. Applicants respectfully submit that most of the compounds included in the list of adjunct ingredients of the '623 patent (ie. alpha-hydroxy acids, retinoids, etc.) are known to those of ordinary skill in the art to be skin irritants. Skin irritants would be expected to redden or inflame the skin, not reduce redness or inflammation. In fact, dimethylaminoethanol is taught to be corrosive to the skin and causes severe eye damage in animals (see paragraph 3.2.3 of the attached Risk Assessment document). The Risk Assessment document states that dimethylaminoethanol, is expected to show similar corrosive effects on the skin and eyes of humans. Applicants have surprisingly found that tyrosine and ethyl-aminoalcohols have anti-inflammatory properties and function to reduce redness on mammalian skin. Furthermore, it is Applicants position that the '623 patent fails to teach or suggest a method for ameliorating redness or inflammation. The patent is clearly drawn to a method of treating acne, not reducing redness or inflammation. Applicants respectfully submit that the rejection under 35 U.S.C. §102 (a) and (e) with respect to the '623 patent is clearly erroneous and respectfully request withdrawal of the rejection.

The Examiner also stated that the present claims are anticipated by the '942 patent. Applicants strenuously disagree. The Examiner has taken a patent that broadly teaches treating scars in the inflammatory stage and concluded that the patent teaches a method for ameliorating redness or

inflammation. Applicants respectfully submit that the patent does not teach or suggest a method for ameliorating redness or inflammation. Nor does the patent teach or suggest the combination of actives selected by the present inventors. As was the case with the '623 patent, the '942 patent lists adjunct ingredients (ie. alpha-hydroxy acids, retinoids, etc.), most of which are known to those of ordinary skill in the art to be skin irritants. Skin irritants would be expected to redden or inflame the skin. Applicants have surprisingly found that tyrosine and ethyl-aminoalcohols have anti-inflammatory properties and function to reduce redness on mammalian skin. Furthermore, the '942 patent teaches that the compositions of that invention prevent cross-linking of cell membranes to reduce keloid scar formation (column 7, lines 56 – 62) and prevent incessant membrane damage (column 8, lines 14 – 20). The patent is clearly drawn to a method of treating scars. There is no teaching or suggestion to reduce redness or inflammation. Applicants respectfully submit that the rejection under 35 U.S.C. §102 (a) and (e) with respect to the '942 patent is clearly incorrect and respectfully request withdrawal of the rejection.

Claims 1, 2, and 10 were rejected as anticipated by the '993 patent. The Examiner asserts that the '993 patent teaches the use of triethanolamine to reduce redness. Applicants respectfully submit that the Examiner has misinterpreted the teachings of the '993 patent. The '993 patent specifically teaches that antioxidants function to treat rosacea (column 4, lines 35 – 38). Suitable antioxidants are listed in column 4, lines 41 – 65. Triethanolamine is not an antioxidant, nor is it listed in the materials that are useful to treat rosacea. The Example cited by the Examiner (column 10, lines 33 – 36) and any other Example of the '993 patent containing triethanolamine also contain tocopherol and lycopene (antioxidants), or other antioxidants. In fact, four of the Examples of the '993 patent do not contain triethanolamine, or any of the compounds of the present invention, yet they are effective for treating rosacea. It is very clear that the '993 patent does not teach the use of triethanolamine to reduce redness, rather, the patent teaches the use of antioxidants to reduce redness. It is well understood to those of ordinary skill in the art that triethanolamine is commonly utilized to form emulsions (triethanolamine base reacts with stearic acid to form emulsion "soap") and not to be an active for irritation reduction. Triethanolamine is also typically utilized to adjust product pH. Triethanolamine by itself is a strong base that is known to be a skin irritant. There is no teaching or suggestion in the '993 patent to reduce redness or inflammation utilizing the compositions of the present invention. Applicants respectfully submit that the rejection under 35 U.S.C. §102 (a) and (e) with respect to the '993 patent is without merit and respectfully request withdrawal of the rejection.

#### The Rejections under 35 U.S.C. §103(a) are Incorrect

Claims 6 and 9 – 15 stand rejected under 35 U.S.C. §103 (a) as unpatentable over '942 in view of '532. As discussed above, the '942 patent lists adjunct ingredients (ie. alpha-hydroxy acids, retinoids, etc.), most of which are known to those of ordinary skill in the art to be skin irritants. Skin irritants would

be expected to redden or inflame the skin. Applicants have surprisingly found that tyrosine and ethyl-aminoalcohols have anti-inflammatory properties and function to reduce redness on mammalian skin. Furthermore, the '942 patent teaches that the compositions of that invention prevent cross-linking of cell membranes to reduce keloid scar formation (column 7, lines 56 – 62) and prevent incessant membrane damage (column 8, lines 14 – 20). The patent is clearly drawn to a method of treating scars. There is no teaching or suggestion from the '942 patent to select the compounds of the present invention for use to reduce redness or inflammation.

The '532 patent does nothing to make up for the deficiencies in the teachings of the '942 patent. The '532 patent does not teach the compounds utilized in the present invention, nor does it teach the use of the compounds of the present invention to ameliorate redness or inflammation. Furthermore, there is no teaching or suggestion in the references to modify the methods taught by the '942 patent. Applicants respectfully submit that the combination of the references does not provide the present invention. Applicants therefore respectfully request withdrawal of the rejection.

**Conclusion**

Applicants believe that the foregoing presents a full and complete response to the present Office Action. Applicants believe that this Response After Final places the case in condition for allowance, therefore Applicants respectfully request entry of this Response into the case and passage of the Claims to allowance. If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-525/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,



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